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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/745,243      | 12/21/2000  | Narendra Parikh      | JBP514              | 8350             |

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/745,243 | <b>Applicant(s)</b><br>PARIKH ET AL. |  |
|                              | <b>Examiner</b><br>Frank I. Choi     | <b>Art Unit</b><br>1616              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-6,8,9,12-14,16-19,21,22,24-27,29-33,35,36 and 73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6,8,9,12-14,16-19,21,22,24-27,29-33,35,36 and 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2005 has been entered.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 24-27, 29, 30 claim a rapidly disintegrating tablet; Claim 16 claims that the first coating layer is substantially free of plasticizer; and claim 24 claims that the first coating layer or second coating layer is substantially free of plasticizers. Although the same was claimed in one or more of the original claims, the Specification appears to disclose tablets in general and chewable tablets but not rapidly disintegrating tablets and there does not appear to be any disclosure as to the coating layers being substantially free of plasticizers.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16-19, 21, 22, 24-27, 29, 30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP

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§ 2172.01. The omitted structural cooperative relationships are as follows. The claims are directed to a tablet, chewable tablet or rapidly disintegrating tablet, however, the only limitations are directed to particles. There are no elements which define a structural relationship between the particles so as to form a tablet, chewable tablet or rapidly disintegrating tablet. Clearly there is a difference between chewable tablets, rapidly disintegrating tablet and tablets per se. A tablet must contain some ingredient that would allow the particles to bind together to form the tablet, and the former two must contain additional ingredients that would allow one to be chewable and the other to rapidly disintegrate. See Specification, pages 9-12. However, the each of the tablet claims do not set forth any elements that are different from the other tablet claims.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in that claim 24 claims that the second coating layer is substantially free of a plasticizer. However, the second coating layer can contain 20-80% of PEG. PEG is a plasticizer. See EP 0 169 319, Page 4, lines 23-34. Although the Specification does not appear to define what is meant by "substantially free", it would appear that at a minimum anything greater than 50% would be a substantial portion of the coating. As such, the dependent claim appears to exclude what that independent claim requires which makes the claim indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-6,8,9,11,13,14,16-19,21,22,24-27,29-33,35,36,73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al. (US Pat. 5,789,014) in view of Zingerman et al. (US Pat. 3,431,138), Friend et al. (US Pat. 6,139,865), CA 2068366 and Norling et al. (US Pat. 5,958,458).

Maruyama et al. disclose that a solid preparation with a coating is used for enteric properties, controlled release, masking bitter tastes, etc. (Column 1, lines 20-23). It is disclosed that the first coating can contain a combination of polymers, such as cellulose acetate phthalate and ethyl cellulose (column 5, lines 35-63). It is disclosed that the solid preparation can be further coated with a granule adhesion preventing agent, including mixtures of agents such as aqueous polymers, such as hydroxypropylmethyl cellulose and polyethylene glycol (Column 6, lines 20-28).

Zingerman et al. discloses that addition of polyethylene glycol to a cellulosic coating composition improves the flexibility and smoothness of the finished coating layer (Column 2, lines 38-43).

Friend et al. disclose the use of ethyl cellulose, cellulose acetate phthalate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs (Column 7, lines 22-39). It is taught that the microcapsules provide dissolution of at least about 90% at 45 minutes (Column 8, lines 36-66). It is taught that the particle size of the microcapsules will be in the range of a few microns up to about 1000 microns or more, with particle sizes in the approximately 30 microns to 800 microns, and the particles sizes in the range of approximately 40 microns to 250 microns particularly preferred and that those skilled in the art will recognize that the components of the microcapsules, the relative quantities of the drug and polymeric coating material, the size of the microcapsules and other parameters, can be easily

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varied to provide of different degrees of taste masking and various release profiles (Column 8, lines 31-43).

CA 2068366 disclose that ethyl cellulose is a water-insoluble polymer and that cellulose acetate phthalate and hydroxypropylmethyl cellulose phthalate are enteric polymers (Pg. 8, lines 26-33, Pg. 9, lines 30-38).

Norling et al. discloses a particle having two or more layers of coating, including film coatings and modified release coatings where the coating provides desired release profile of the active substance or masks the bad-tasting active substances (Column 8, lines 36-68, Column 9, Column 10, lines 1-34).

The prior art discloses a solid preparation containing a first coat containing a mixture of ethyl cellulose and cellulose acetate phthalate and a second coat containing a mixture of HPMC and PEG. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using the ratio of HPMC to PEG of about 80:20 to about 20:80. However, the prior art amply suggests the same as the prior art discloses the combination of the same and that polyethylene glycol added to a cellulosic coating composition improves the flexibility and smoothness of the finished coating. As such, it would have been well within the skill of one of ordinary skill in the art to combine various amount as desired to provide a desired smoothness of the second coating layer.

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection.

Reference JP-2-53271 is no longer part of the rejection herein. Further, the affidavit (10/21/2005) is not sufficient to overcome the rejection herein. The Affidavit compares a ratio of 80:20 HPMC:PEG to 93:7 HPMC:PEG, and indicates that the 80:20 ratio had better texture

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than the 93:7 ratio. The prior art, however, discloses that polyethylene glycol is added to increase flexibility and smoothness of the finished coating. As such, it is not unexpected that reducing the amount of PEG would result in the coating being less smooth. As such, the affidavit does not show unexpected results. Further, the evidence submitted is not commensurate in scope with the claims. The claimed range is about 80:20 to 20:80 and includes any film forming polymer with the polyethylene glycol or polyethylene oxide anti-grit agent; whereas, the evidence submitted only compares the 80:20 HPMC:PEG to 93:7 HPMC:PEG. See *In re Clemens*, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at “elevated temperatures” using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term “elevated temperatures” encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalyst containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.). Further, to establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside

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and outside the claimed range to show the criticality of the claimed range. In re Hill, 128 USPQ 197 (CCPA 1960).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

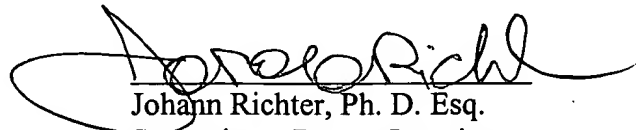
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 25, 2006

  
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